DEC 5 2005

510(k) SUMMARY

K NUMBER

SPONSOR

DuoProSS Meditech Corporation
27 Sarah Drive
Farmingdale, NY 11735
Phone: 631.249.0100
Fax: 631.249.0700

SUBMITTED BY

Ferguson Medical
Consultant to DuoProSS

CLASSIFICATION NAME

Needle, Hypodermic, Single Lumen

CLASSIFICATION NUMBER

21 CFR 880.5570/Procode 90 FMI

PROPRIETARY DEVICE NAME

DuoProSS Needle

DEVICE DESCRIPTION

The DuoProSS Needle device is a sterile, single use, standard hypodermic needle. The device is available in various Gauges and lengths.

Each needle device consists of a stainless steel cannula sealed with epoxy glue into a polypropylene hub. The assembly has a protective polypropylene needle shield. The device is packaged in a peal-back pouch and sterilized by ethylene oxide.

DESIGN AND MATERIALS

The DuoProSS Needle device consists of 4 parts or materials: a stainless steel cannula, a polypropylene hub, epoxy glue and a polypropylene needle guard. Please see List of Components and Materials table.

INTENDED USE

The DuoProSS Needle device is a sterile hypodermic needle intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.

SUBSTANTIAL EQUIVALENCE

Terumo Disposable Hypodermic Needle (K771203) and others.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 5 2005

DuoProSS Meditech Corporation
C/O Mr. Frank Ferguson
Official Correspondent
Ferguson Medical
12200 Academy Road N.E. # 931
Albuquerque, New Mexico 87111

Re: K052445
Trade/Device Name: DUOPROSS NEEDLE
Regulation Number: 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: November 23, 2005
Received: November 28, 2005

Dear Mr. Ferguson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276- 0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K052445

Indications For Use

510(k) Number (If known): K052445

Device Name: DUOPROSS NEEDLE

Indications For Use:

The DuoProSS Needle device is a sterile hypodermic needle intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.

Prescription Use ___XX___ And/Or Over-The- Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

William M. Burdick
For Anthony D. Watson 12/5/05
...on Sign-Off)
...of Anesthesiology, General Hospital,
...ction Control, Dental Devices
...Number: K052445